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A5R

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(54) Making artificial limbs

(57) In a method of making an artificial limb, a positive impression of an amputated limb stump is produced by first surrounding the stump with a hollow flexible jacket containing polystyrene beads in an inner compartment, inflating an outer compartment if necessary to compress the jacket against the stump, and evacuting the inner compartment so that the beads form a rigid mass moulded to the shape of the stump. The jacket is removed from the stump with the negative pressure in the inner compartment maintained, and is used as a mould for casting a positive plaster impression of the stump which may be used for vacuum forming a definitive thermplastics socket. The evacuated jacket, whilst still fitted to the stump, is used as a temporary artificial limb socket for alignment purposes. This is achieved by coupling a temporary distal artificial limb portion including an alignment device to a proximal end portion of the jacket, for example with a casting brim fastened to the jacket, to form a complete temporoary limb for performing a dynamic trial. This enables the prosthetist to establish alignment settings which are preserved during the casting of the positive impression, and are automatically transferred to the definitive artificial limb.

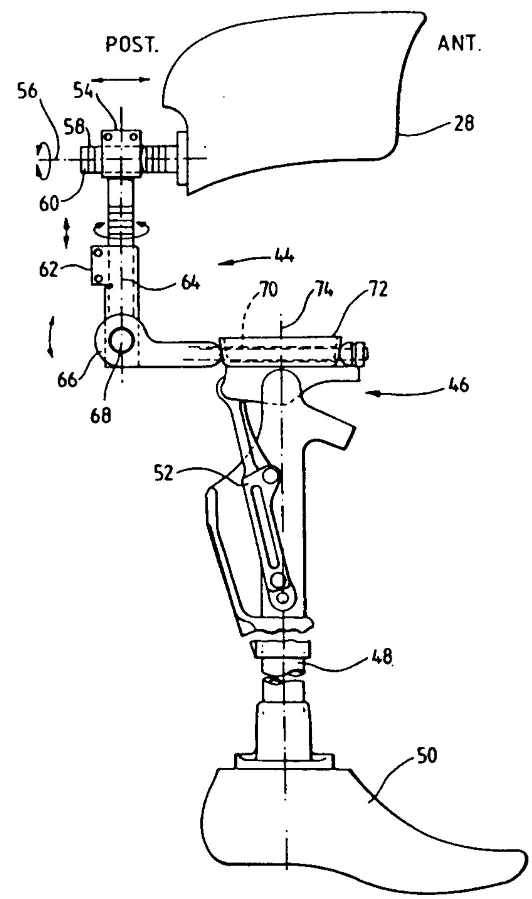

Fig.9.

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SPECIFICATION

Improved method and apparatus for manufacturing an artificial limb

This invention relates to artificial limbs and in particular to the initial production stages of an artificial limb.

A well known method of making a socket for an artificial limb includes forming a plaster-of-Paris cast of the patient's amputated limb stump by building up layers of plater-impregnated bandage on the stump and then allowing the cast to harden. The cast is used as a mould for casting a positive plaster impression of the stump, which in turn may be used as a mould for forming a definitive plastics socket, for example by vacuum-forming. In the case of a socket for an above-knee or through-knee amputee the prosthetist often fits an adjustable casting brim around the proximal portion of the stump and builds up the plaster bandage cast so that it overlaps or fits underneath the brim. The brim is held at the required height relative to the stump by a support standing on the floor. The resulting combination of the brim and the hardened plaster cast forms the mould for making the positive plaster impression.

One of the main disadvantages of this known process is that the patient is required to stand for a relatively long period, often for as long as one hour, while the plaster mould is built up and allowed to harden.

A further disadvantage is that the method can produce variable results requiring later modelling of the positive impression, since the pressure applied to the stump when the plaster bandages are being laid up often varies from one part of the cast to another according to the pressure applied by the prosthetist.

Conventionally the making of a plaster bandage mould of the stump occurs during the first of at least three visits the patient must make to a limb fitting centre. Between the first and second visits the positive plaster impression of the stump is cast with the plaster bandage mould mounted in a so-called duplicating jig, with an alignment device and, in the case of an artificial leg, a shin tube clamped in position beneath the mould. The position of the jig relative to the shin tube is then adjusted by eye and a rod, attached to the jig coaxially with the shin tube, is lowered into the mould. Liquid plaster is poured into the mould to form a positive impression of the stump located on the rod, this positive impression then being removed from the original plaster bandage mould to act as an internal mould for vacuum forming a definitive plastics socket. Before the socket is formed, the positive impression will have had an interfacing component attached at the distal end as a means of mounting the distal part of the limb to the finished socket. The vacuum formed socket is mounted on a temporary or definitive limb including an alignment device, and the patient then pays a second visit to the fitting centre for a walking trial during which a full alignment of the limb is caried out. Agter the second visit, a cosmetic covering is fitted and the limb finished off for final delivery. At the third visit final adjustments are performed and the patient takes delivery of the limb.

It is an object of this invention to reduce the amount of time spent by the prosthetist, and the time and inconvenience for the patient during the above described procedure.

According to a first aspect, the invention provides an artificial limb fitting method in which a temporary limb socket is moulded in situ on a patient's amputated limb stump, and is coupled in the region of its proximal end to a temporary artificial limb portion including an alignment device, and in which the combination of the socket and the artificial limb portion is used on the patient to establish alignment settings of the socket relative to a distal part of the artificial limb portion by making adjustments with the alignment device. In this way, an artifical leg patient, for example, is provided with means enabling him or her to stand and walk at a much earlier stage than has been possible with prior art methods, allowing the prosthetist to carry out measurements and to make adjustments to the fit of the socket in its loaded stage before a definitive socket is moulded and to establish alignment settings that can be carried through into the definitive limb as will be described below. This early alignment and fitting procedure in many cases reduces the number of visits a patient has to make to the fitting centre to two. The method although intended primarily for use with an evacuated jacket, can also be carried out with the plaster bandage mould.

Alignment settings established by the above method may be transferred to the definitive limb by casting the positive impression in the temporary socket whilst the latter is still attached to the temporary limb portion. A reference member, held in a duplicating jig in a defined position relative to the distal limb portion, is embedded in the position impression so that the same position relationship can be reproduced when the definitive socket moulded on the impression is mounted on the definitive distal limb portion.

Having transferred the initial 'trial-based' settings to the definitive limb, the extent of further adjustments necessary on the patient's second visit is comparatively minor, often enabling the limb to be ready for delivery at that visit.

In this connection, a second aspect of the invention provides a temporary artificial limb comprising a temporary limb socket moulded in situ on the patient's amputated limb stump, and, coupled to a proximal end portion of the

socket, an artificial limb portion including an alignment device for establishing alignment settings of a distal part of the limb portion relative to the socket whilst the socket is fitted to the stump.

According to a third aspect of the invention, a dynamic alignment jig for performing artificial limb alignment tests with a temporary socket moulded in situ on a patient's amputated limb, comprises an annular proximal casting brim, an alignment device attached to the brim, and a distal limb position, the alignment device being operable to adjust the orientation of the brim relative to the distal limb portion.

The invention will now be described by way of example with reference to the drawings, in which:–

Figure 1 is a perspective view of a first embodiment of a device for casting an impression of an amputated limb stump;

Figure 2 is a longitudinally sectioned side view of the device of Fig. 1;

Figure 3 is a transversely sectioned plan view of the devices of Fig. 1 shown applied to the stump;

Figure 4 is a perspective view of the device of Fig. 1 attached to a casting brim for an above-knee amputee;

Figure 5 is a diagrammatic longitudinally sectioned side view of a second device for casting an impression of an amputated limb stump;

Figure 6 is a plan view of the device of Fig. 5;

Figure 7 is a perspective view of a third device for casting an impression of an amputated limb stump;

Figure 8 is a transversely sectioned plan view of the device of Fig. 7;

Figure 9 is a side view of part of a temporary artificial limb in accordance with the invention; and

Figure 10 is side view of a temporary artificial limb mounted in a duplicating jig.

Referring to Figs. 1 to 3, a flexible bag for making a mould in which an impression of an amputated limb stump can be cast has an inner wall 10 and an intermediate wall 12 defining a hollow inner jacket. The space between the walls 10 and 12 is loosely filled with polystyrene beads 14, which form a shapeless and manipulable mass at atmospheric pressure, but bind together to create a rigid mass when air is drawn out of the jacket through a pipe 16 communicating with the interior of the jacket.

The bag also has an outer hollow jacket defined by an outer, preferably flexible wall 18 and the intermediate wall 12. This jacket has no filling, and is arranged around the inner jacket so that when pressurised via pipe 20, the inn r jacket is compressed against the stump 28 (Fig. 3).

Th three walls, 10, 12 and 18 are all made of flexible rubber or translucent plastics sheeting, and are heat welded together in the region of the open proximal end 22 of the bag along an annular weld line 24. One of the walls is extended above the weld line to form a flexible skirt portion 26.

When the bag shown in Figs. 1 to 3 is applied to the patient's stump, the skirt portion 26 is secured to metal or plastics casting brim 28 as shown in Fig. 4, preferably so that the inner jacket overlaps the lower edge of the brim. The brim shown is a conventional piece of apparatus normally used as the base for building up a plaster bandage mould around the stump. It has two lugs 30 for a floor standing support. Fastening means, in this case press studs 32, are provided for attaching the skirt portion 26, to form a complete temporary socket, which in addition to its main function as a mould, can also be used, as will be described hereinafter, as a part of a temporary artificial limb for testing and alignment purposes, further artificial limb components being attached to the lugs 30.

Although press studs 32 are shown, alternative means of connecting the brim to the bag may be used, such as a pull cord threaded through the skirt portion 26, or a band clamp encircling the brim. It is also possible with a thermoplastics brim to heat weld it permanently to the bag.

With the bag and brim in position on the stump, the inner jacket is uniformly compressed against the stump to a required degree by pressurising the outer jacket via pipe 20. At the same time, any uneven distribution of the polystyrene beads 14 can be corrected by blowing air into the inner jacket to disturb the beads and spread them uniformly around the stump. Then, with the outer jacket pressurised, air is evauated from the inner jacket to bring the beads together in a cohesive rigid mass having an interior surface which is moulded to the shape of the stump. At this stage the bag and brim can be used as part of a temporary limb for a walking trial. Subsequently, with the negative pressure in the inner jacket maintained, the bag and the brim are removed together from the stump so that a plaster impression of the stump can be cast inside. If necessary, prior to casting, the interior surface of the bag can be modelled (it may be necessary to reduce the vacuum to do this) to relieve pressure points for instance.

The bag shown in Figs. 1 to 3 is only one form of device which may be used. A sleeve such as that shown in Figs. 5 and 6 may be preferred. As with the bag, this sleeve is a two-jacket device housing an inner jacket filled with polystyr ne beads 14, and an outer jacket for applying pressure to the stump. However, in contrast to the device of Figs. 1 to 3, th jackets are initially formed individually, so that when the outer jacket is fitted over the inner jacket the boundary between

the two jack t interiors is a double skin 34. The two jackets can be welded together if required but this is not essential. In other respects the construction is similar, with pipes 16 and 20 connected to respective jacket interiors, although here non-return valves 36 and 38 are included for maintaining the required positive and negative pressures.

One advantage of the sleeve construction is that it allows the tissues of the stump to be pulled towards the distal end. This can be beneficial to load distribution across the surface of the stump. The stretching of the tissues may be performed by first slipping a normal drawn-down sock over the stump. The sleeve is attached to a casting brim, and the brim and socket are fitted together around the stump. By subsequently withdrawing the sock downwardly, the tissues of the stump are stretched towards the end of the stump, especially if this is done when the outer jacket is pressurised. Then, as before, the pressure in the outer jacket is adjusted to the required level, and the inner jacket evacuated via valve 36. A pad (not shown) may be placed on the end of the stump prior to evacuation to provide an internal cap which prevents liquid plaster from flowing out of sleeve during casting and may provide an end bearing from the stump.

A further device is shown in Figs. 7 and 8. This has a relatively simple single jacket bag construction, and incorporates a zip 40 and welded hinge line 41. The zip and hinge line are included so that the bag can be removed more easily from stumps having a bulbous end, such as produced by through-knee amputation.

Referring to Figs. 9 and 10, the method and apparatus of the invention whereby a temporary socket, such as that formed by the casting device and brim referred to above, can form part of a temporary artificial limb for testing and alignment purposes will now be described.

Such a temporary limb for an above-knee amputee is shown in Fig. 9, minus the casting device. The limb includes an alignment device 44 fixed to a proximal casting brim 28. The brim 28, as described above, includes means such as press studs, clamps or ribs (not shown) for attaching the temporary in situ casting device such as the evacuable bag or sleeve disclosed above. The alignment device 44 is fixed to a distal limb portion comprising a knee joint 46, a shin tube 48, and a foot 50 which is adjustably mounted on the shin tube 48 to allow setting of the shin length. The knee joint is a known unaixial type including a knee locking device 52. However, many of the alignment and testing operations possible with this limb can be carried out with a simpler structure having no knee joint.

The alignment device 44 is mounted on the posterior surface of the brim 28 and is similar to that disclosed in our copending Application No. 81 25811. A first screw clamp 54 allows anterior/posterior shift of the brim and adduction/abduction movements about the horizontal axis 56. Calibration marks 58 are provided on the shaft 60. A second screw clamp 62, permits rotation about the vertical axis 64 and height adjustment. A third clamped joint 66 provides for flexion/extension setting above axis 68 and medial/lateral setting along axis 68. A pair of bolts 70 secure the alignment device 44 of the knee joint 40 via a cup member 72. The latter is rotatable about the axis 74 to provide a further alignment facility.

The knee joint 46, shin tube 48 and foot 50 can, advantageously, be the actual components which will be used in the patient's definitive limb.

When the prosthetist has had the patient stand and walk on the temporary limb, and has carried out adjustment with the alignment device 44 to the optimum position, the complete limb is removed from the patient and clamped in a duplicating jig 76 as shown in Fig. 10. The shape of the patient's stump is retained in the casting device 78, and the alignment of the temporary socket formed by the brim and the casting device 78 relative to the distal limb portion (the shin tube 48) is retained in the clamped settings of the alignment device 44.

One clamp 80 of the duplicating jig 76 secures the shin tube 48, and the other clamp 82 secures a rod 84 which acts as a reference member held coaxial with the shin tube 48. Thus, when liquid plaster is poured into the temporary socket 28, 78, the rod 84 is embedded in the resulting positive impression, so forming a datum for pre-aligning the definitive limb.

The next stage is the removal of the temporary socket 28, 78 and the attached limb components from the positive impression. The positive impression is then used to vacuum form a definitive plastics socket while the temporary socket and limb components can be used again on another patient.

Final mounting of the definitive socket on the definitive lower limb is performed in the duplicating jig with the lower limb held in a defined position in the clamp 80, and the socket, still with the positive impression inside it, mounted in a defined position by the clamp 82 holding the rod 84. It will be seen that the positional relationship between the socket and the lower limb corresponds to the original relationship between the temporary socket and limb components. This means that when the socket is mounted in the definitiv limb, the limb can be finished off to a stat in which it is virtually ready for delivery, in the knowledge that only relatively minor adjustments will be required when it is fitted to the patient.

CLAIMS

1. An artificial limb fitting method in which a temporary limb socket is moulded in situ on a patient's amputated limb stump, and is coupled in the region of its proximal end to a temporary artificial limb portion including an alignment device, and in which the combination of the socket and the artificial limb portion is used on the patient to establish alignment settings of the socket relative to a distal part of the artificial limb portion by making adjustments with the alignment device.

2. A method according to claim 1, wherein the in situ moulded socket and the temporary limb portion are removed from the stump as a unit and supported in a duplicating jig with a positional reference member held inside the socket, and wherein an impression of the stump is cast in the socket with the reference member embedded in the cast impression.

3. A method according to claim 2, wherein the cast impression is removed from the temporary socket and a definitive socket is moulded over the impression, and wherein the combination of the definitive socket and the impression is again mounted in the duplicating jig which also supports a definitive artificial limb portion so that when the definitive socket and the definitive limb portion are coupled together the alignment of the definitive socket relative to the definitive limb portion substantially corresponds to the previously established alignment settings.

4. A temporary artificial limb comprising a temporary limb socket moulded in situ on the patient's amputated limb stump, and, coupled to a proximal end portion of the socket, an artificial limb portion including an alignment device for establishing alignment settings of a distal part of the limb portion relative to the socket whilst the limb is fitted to the stump.

5. A temporary artificial limb according to claim 4, further comprising a casting brim fastened to the proximal end portion of the socket, the alignment device being mounted on the brim and extending alongside the socket.

6. A dynamic alignment jig for performing artificial limb alignment tests with a temporary socket moulded in situ on a patient's amputated limb stump, wherein the jig comprises an annular proximal casting brim, an alignment device attached to the brim, and a distal limb portion, the alignment device being op rable to adjust the orientation of the brim relative to the distal limb portion.

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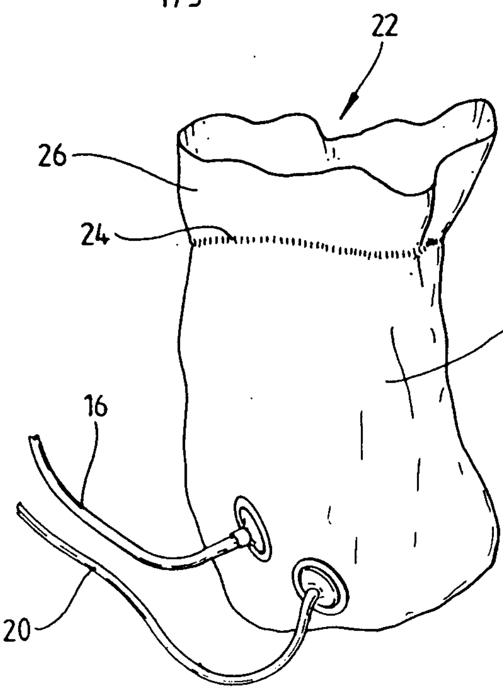


Fig.1.

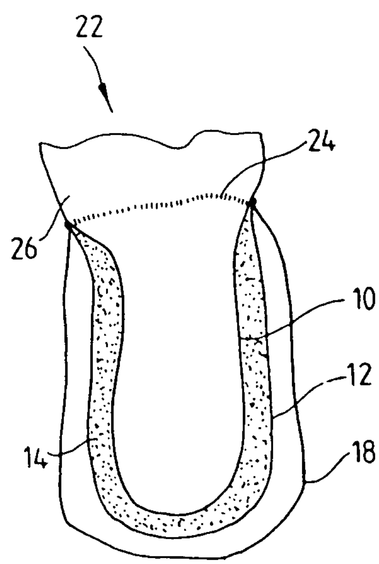


Fig.2.

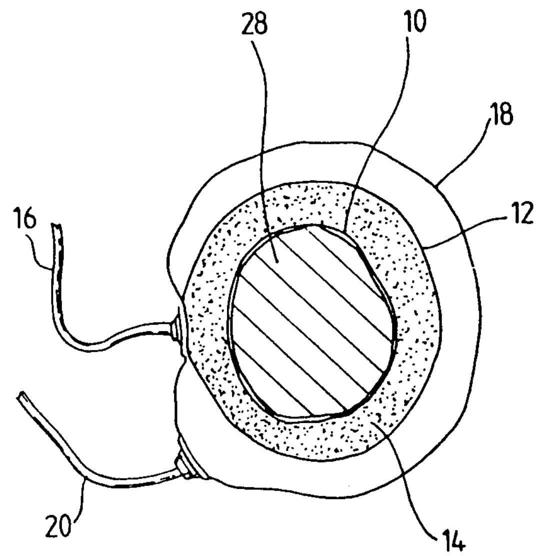


Fig.3.

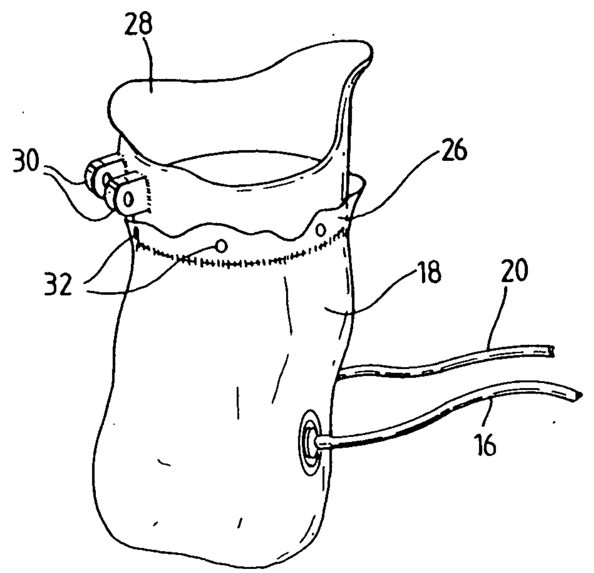


Fig.4.

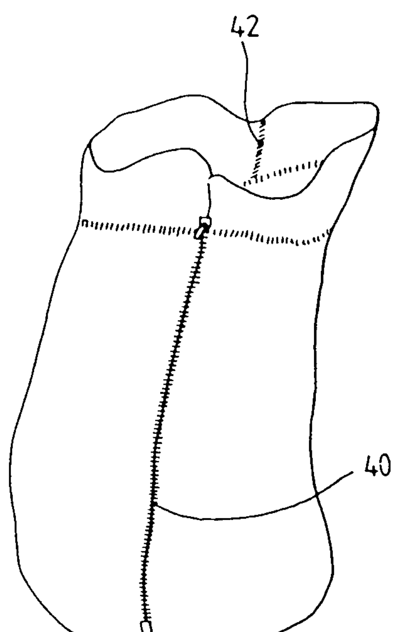


Fig.7.

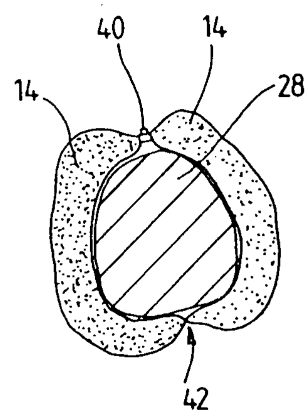
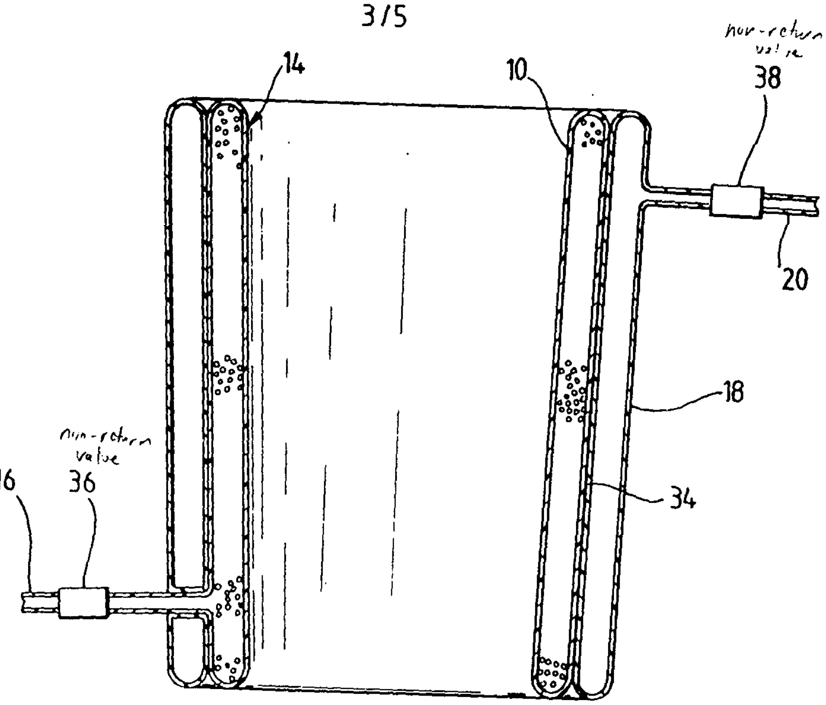


Fig.8.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non-return valve
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18
non-return valve
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Fig.5.

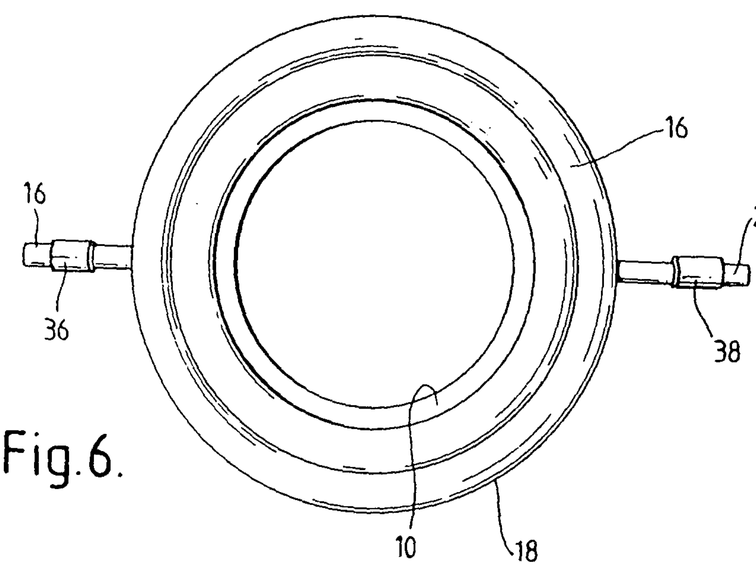
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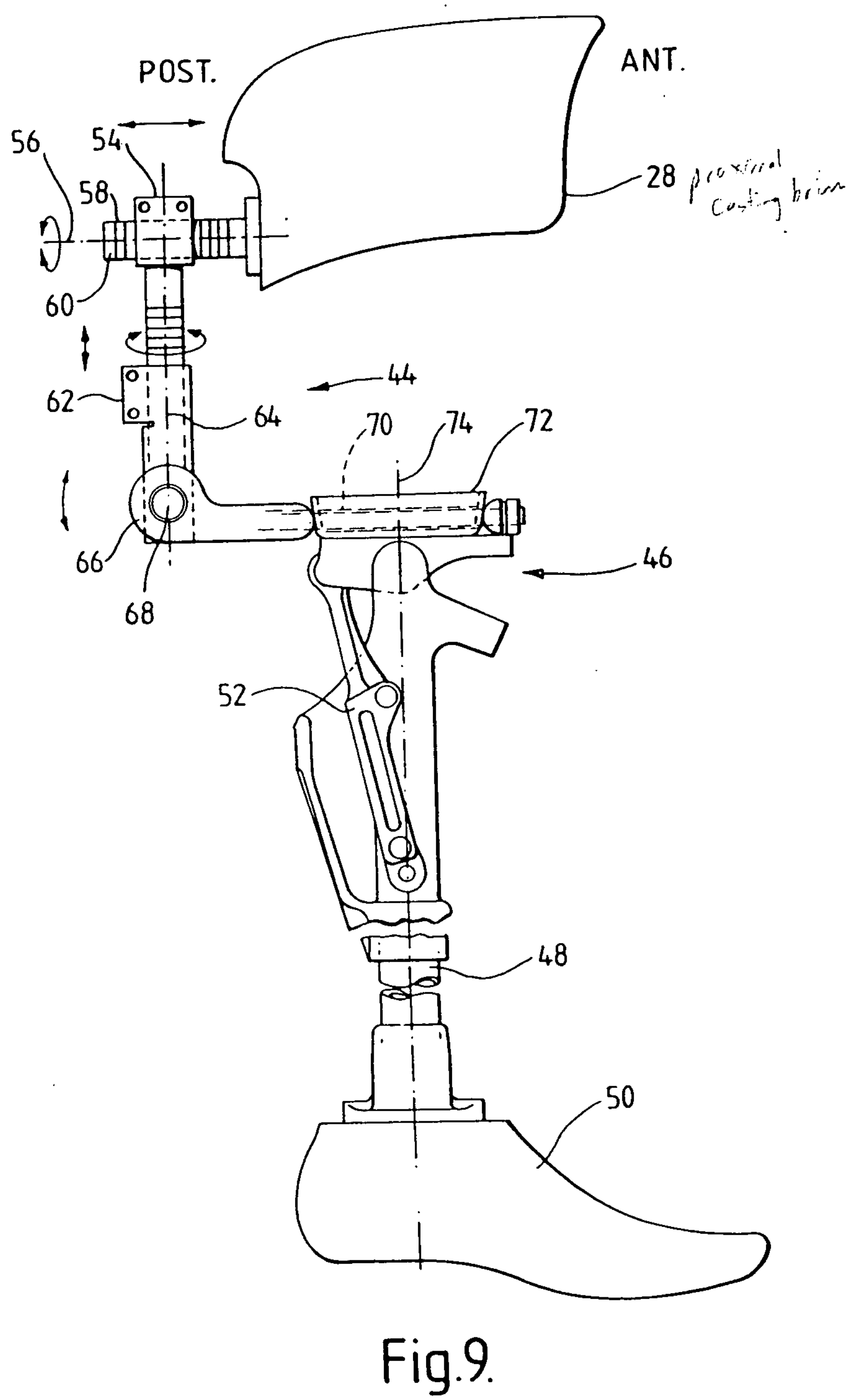
Fig.6.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proximal casting brim
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Fig.9.

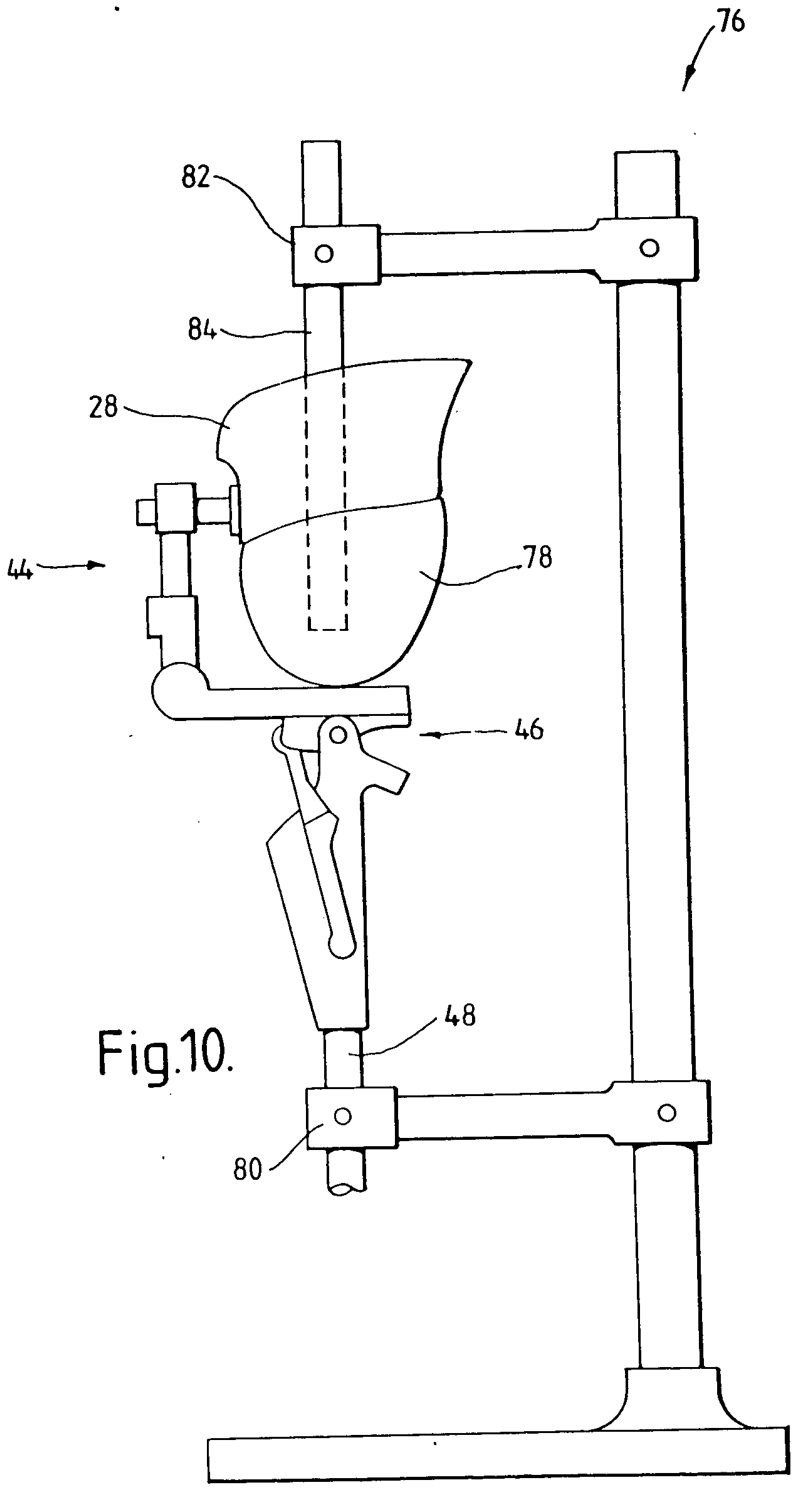

Fig.10.